

# Risk Assessment: A Means for Linking HACCP Plans and Public Health

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## ABSTRACT

HACCP plan adoption has greatly enhanced the food industry's ability to systematically design programs to ensure the microbiological safety of foods. Yet, this widening acceptance of the HACCP system has revealed several areas where its application is limited due to reliance on qualitative consideration of hazards and their control. In particular, HACCP planning is limited both conceptually and practically by its inability to quantify the potential combined influence of multiple control-point deviations and to relate the successful operation of a HACCP system to a measurable public-health impact. Recent advances in quantitative microbiological risk assessment appear to offer a means of overcoming these limitations. The integration of HACCP plans with the development of dynamic risk-assessment models offers a means for considering the entire farm-to-table continuum and for relating food-manufacturing operations to public health goals. Such capabilities may be critical to establishing equivalence among HACCP systems.

Since its introduction in the early 1970s, HACCP (hazard analysis critical control point) plan application has become the premier system for evaluating and controlling foodborne hazards, particularly those of microbiological origin (6). The basic process in creating HACCP plans is that significant hazards associated with a food product are determined, and then the key steps (i.e., critical control points) in the production, processing, distribution, marketing, and preparation of a food that must be controlled within preestablished boundaries to ensure safety are identified. A program of monitoring, verification, record maintenance, and contingency planning is then developed and implemented to ensure the integrity of the assignment of critical control points. These operating precepts have been organized into a set of seven principles that have been widely accepted internationally as providing the framework for HACCP planning (5).

Unlike the mythological Minerva, the HACCP concept did not spring fully mature from the heads of its originators. Instead, it evolved and matured over the past 25 years, reflecting the broadening application of HACCP plans, in relation to both the categories of food products and the scope of the factors considered. Originally, HACCP systems were targeted at processed products and were limited almost exclusively to the manufacturing environment. However, the inclusion of production of a variety of raw agricultural commodities occurred in recent years. Likewise, HACCP systems are increasingly being extended to encompass the

entire farm-to-table continuum. The expanded role and scope of HACCP systems have been accelerated by its inclusion in national food-safety regulations and guidelines for international trade. These new applications have revealed areas where initial HACCP concepts were incomplete or needed further clarification. For example, verification is a HACCP principle that was vaguely defined initially and required further refinement with increased implementation of HACCP programs.

While the acronym HACCP is unique to the food industry, its principles are not (8). HACCP planning is a form of process control quality assurance. As such, it is based on the same quality assurance and process control principles and statistics used in the manufacture of a wide range of goods. Alternatively, HACCP plan implementation can be viewed as a system for controlling risks. In the risk analysis lexicon, HACCP is a quantitative risk-management system developed on the basis of a qualitative risk assessment.

## HACCP LIMITATIONS

Further development of HACCP concepts and application is required in order to realize its full potential as a systematic approach for assuring the microbiological safety of foods. One area with considerable HACCP system shortcomings is the control of foodborne pathogens on raw agricultural commodities. As mentioned above, the initial application of HACCP systems was to thermally processed, ready-to-eat foods such as low-acid canned products. With such foods, a step lethal to microorganisms is applied during production that has an overwhelming positive impact on risk reduction. HACCP plans for canned foods are relatively

simple. There are two CCPs: the integrated lethality of the thermal process and the integrity of the packaging system that prevents recontamination. Production of foods that are marketed raw typically lacks a definitive lethal step that can be relied on to eliminate microbiological risks. Instead, there is a series of operations or practices that prevent or decrease contamination and limit microbial growth. Ideally, these operations reduce overall risks; however, with some foods prevention of increased risks may be all that can be reasonably expected. For example, the processing of most meat, poultry, and produce includes one or more surface disinfection steps that are capable typically of reducing pathogen levels by one or two log cycles. Otherwise, proper evisceration can only prevent a relatively clean carcass from becoming contaminated.

While a HACCP plan focuses on CCPs as the high-impact steps in food production and processing, each unit operation in that chain affects the overall microbiological profile of the product. Intuitively, one can imagine that for raw commodities if a sufficient number of control points (CPs) were out of control, the resulting hazard might overcome the relatively small risk reductions provided by the CCP steps. However, because HACCP plans are generally based on qualitative hazard analyzes, it is difficult to estimate the likelihood that multiple deviations in precautions observed at CPs could influence CCP operation efficacy, which can occur even with products that are subjected to an overwhelmingly lethal step. For example, for the canning of low-acid foods, it is assumed that the initial spore load is low and the cans are "hot filled." If these CP assumptions are not correct and the proper procedure is not achieved, there is a possibility that the CCP operation, retorting, may be inadequate. Since the general approach to HACCP system development is to err on the side of safety, uncertainty of this type often leads to HACCP plans with excessive numbers of CCPs or to overly conservative application of lethal treatments at CCPs.

A second and more important limitation to the development and implementation of HACCP programs is our inability to directly link their impact to public health. Since the goal of HACCP plan implementation is to reduce foodborne human disease, the ideal yardstick of its effectiveness is a measurable reduction in the number of cases of foodborne illness. However, current measures of HACCP efficacy are based on selected technological capabilities such as the determination of temperatures or *Salmonella* CFU counts. This inability to directly measure the effectiveness of a HACCP plan in terms of its ultimate goal (preventing illness) has several implications, two of which will be discussed further.

The first limitation associated with the inability to relate HACCP plans to public health goals is in relation to the HACCP principle 3 (5), "establish critical limits." Each CCP has one or more critical limits upon which decisions concerning whether a process is in control or not are based. Typically, critical limits are based on one or more physical or chemical attributes (e.g., time and temperature of cooking, pH of a formulation, water activity) which relate to a microbiological criterion (e.g., a thermal process capable of

reducing the number of *Salmonella* CFU by 7 D, or a reduction in temperature such that the generation time of *Listeria monocytogenes* is greater than 24 h) (1). The stringency of a HACCP plan is established through the selection of critical limit values. However, because the HACCP operation is both based on a qualitative risk analysis and cannot be linked to its public health goals, establishing critical limits that set a desired level of stringency for a HACCP program is largely a matter of guesswork. Terms like "reduce to an acceptable level of risk" (5) become virtually meaningless if that risk cannot be measured.

A second derivative limitation stemming from our inability to relate public health goals and HACCP programs is in the area of equivalence. It has long been recognized by the developers of HACCP concepts that there is great diversity in the food industry and multiple means to achieve the same level of safety. Even if two plants make virtually identical products, it is unlikely that they have the same geographical location, ingredient sources, facilities layout, equipment, process, etc. This diversity is the reason that HACCP plans must be product, plant, and even production-line specific. Relying on generic HACCP plans is insufficient because they cannot deal with the unique characteristics of individual plants. While diversity must be assumed, it is also reasonable to expect that the various HACCP programs for a food product should achieve some minimal level of equivalence, i.e., provide the same level of public health control or degree of risk management. Further, it is desirable from risk management, regulatory, and international trade perspectives to be able to apply similar levels of safety stringency among different foods, thereby establishing the proverbial "level playing field." However, the farm-to-table diversity within the food industry can be so large that attempting to establish safety equivalence would be virtually impossible unless the focus is on a common measurable goal such as public health risk.

#### APPLICATION OF QUANTITATIVE MICROBIAL RISK ASSESSMENT TO HACCP SYSTEMS

Recent advances in quantitative microbial risk assessment (QMRA) concepts and techniques expand its HACCP system applications, particularly to overcome the limitations discussed above. Some of the obvious applications of QMRA to the development and implementation of HACCP programs are in the performance and interpretation of hazard analyzes, the establishment of critical limits, the estimation of the overall stringency of HACCP programs, and the development of plans for the disposition of products produced under periods of process deviations. However, concerns have been raised about both the appropriateness of applying QMRA at this level and the degree of sophistication and information needed by food manufacturers to successfully achieve the integration of the two systems.

To date, most risk assessments of foods or agricultural commodities have been by government agencies on broad policy issues, such as the establishment of residue tolerances for agricultural pesticides or food additives or the importa-

tion of agricultural commodities from regions known to harbor plant or animal pathogens. There are proponents who recommend limiting QMRA applications to that level. However, the question of application level should be viewed in relation to the reason for conducting risk assessment, i.e., to provide information sufficient to make informed risk-management decisions. If, as is the case with most microbial food-safety issues, risk management decisions must be plant or product specific, then the usefulness of broad, industry-wide risk assessments is severely limited. This concept has been long recognized in HACCP applications, where both the hazard analyses and subsequent risk management decisions concerning, e.g., the choice of CCPs or critical limits, are on a plant-specific basis. However, application of this concept does not mean that each company would need to provide all of the data required to conduct a QMRA. With the possible exception of a few multinational corporations, such an undertaking is well beyond the capabilities of individual food companies. Instead, companies could rely on government agencies, international bodies, or trade organizations to provide data such as dose-response relationships, baseline data for pathogen occurrence levels in various commodities and products, consumption patterns, and consumer demographics. Likewise, mathematical models needed to describe the growth, survival, and inactivation of various foodborne pathogens have already been developed by scientific teams in several countries. These general data could then be combined with product- or plant-specific data such as ingredient sources, processing parameters, distribution systems, and product shelf life to generate risk assessments that support the development of HACCP systems.

HACCP planning is already an information-intensive process. Moving from a qualitative hazard analysis to a quantitative risk assessment increases both the extent of the data needed and the sophistication required of the team performing the evaluation. Does this further refinement of the hazard assessment process provide advantages that warrant the increased work? There is nothing essentially different in qualitative and quantitative analyses. In fact, virtually any qualitative attribute can be described mathematically. For example, it is quite feasible to differentiate pathogens as highly, moderately, and weakly infectious and assign a weighting value to the different classes. However, without some objective measure of infectivity, the confidence in these designations is low. Two key advantages that come from using a quantitative approach are the ability to link the HACCP plan to an estimate of public health impact and a measure of the level of confidence that the evaluators have in their results. These closely related factors are essential to overcoming current HACCP plan limitations.

Dealing with the variability inherent in foods and food systems is one of the greatest challenges when trying to implement risk management systems for controlling microbial food safety. Qualitative hazard analyses cannot address variability in any meaningful manner. The traditional means of dealing with this limitation has been either to ignore it or to base the requirements for the individual steps of a food process on a worst-case estimate. The former approach can

result in a HACCP system that can be predicted to fail periodically due to unaddressed variability, whereas the latter approach is often overly conservative. By combining QMRA and HACCP concepts, investigators are demonstrating that it is possible to develop dynamic risk-assessment models that actively consider process and product variability through the use of computer simulation techniques (2, 7). It is becoming apparent from these efforts that microbial food safety failures often result from combinations of low-probability events associated with steps that have an inherently large variability. A key advantage of implementing HACCP systems is the resulting decreased variability due to a focus on process control (3). This has the effect of eliminating the combinations of low-probability high-risk events of concern.

The development of dynamic risk assessment models has the potential for providing several distinct enhancements to the HACCP process. The goal of dynamic risk-assessment models is to describe effectively the entire farm-to-table continuum, considering each step that influences the overall risk. Such models are not limited to a small number of CCPs, but can sequentially link a series of probabilistic or predictive microbiology models to describe each of the unit operations associated with the process. The advantage predictive microbiology brings to QMRA is that each step can be defined by a continuous quantitative model with its parameters (e.g., time or temperature) instead of being described by a discrete probability of growth versus no-growth node.

A particularly important benefit of using dynamic risk-assessment models when developing HACCP plans is in the identification of CCPs and the establishment of critical limits. The ability to include the variability associated with each of these steps, to perform sensitivity analyses, and to conduct failure scenarios potentially provides a more analytical approach to identifying CCPs. The impact of both CPs and CCPs can be integrated to consider the overall effectiveness of the entire process. This enhanced ability to describe food production and manufacturing brings us closer to the goal of HACCP systems, control of hazards through process control. This capability is critical to determining the likelihood that extreme values of several CP distributions could occur simultaneously and result in a situation where the performance characteristics of a process at a CCP would be overcome. Such analyses, which are a commonly available feature of the software used for Monte Carlo simulation modeling, allow the impact of individual steps on the overall microbial safety of the product to be estimated quantitatively, both in terms of the process's inherent variability and its robustness. While decision trees and related tools have their uses in hazard analyses and are useful in the identification of CCPs (5), as qualitative tools they are unable to provide a continuous measure of the extent of control provided by a process at an individual CCPs. Similarly, by using dose-response models in combination with data on consumption and consumer practices, it is possible to have the output of dynamic models be a measure of public health impact (2, 7).

Another potential benefit of successfully integrating the

use of dynamic risk assessment models into HACCP systems is the ability to evaluate rapidly the impact of changes in ingredients, formulations, and processing parameters on the microbiological safety of the food product. Both HACCP plans and traditional risk assessments are based on taking a snapshot in time. However, processes and products seldom remain constant. One of the practical questions that arise concerning HACCP plans and traditional risk assessments is how much of a change can occur before there is a need to generate new HACCP plans or risk assessments. Dynamic models makes this process much easier. Typically, new data or alternative functions for new or modified processes can be included in the models readily. In fact, this process can be used to explore alternative approaches to food manufacturing to estimate the impact of changes on microbiological safety.

### CONCLUDING REMARKS

HACCP planning has the potential to dramatically improve food safety by focusing efforts on controlling ingredients and key steps in the production and processing process. However, as application of this approach has become increasingly more sophisticated, areas where HACCP systems could be improved are being identified. Recent advances in quantitative microbial risk assessment appear to provide a means for achieving these improvements. In particular, dynamic microbial risk-assessment models that incorporate simulation techniques provide, for the first time, a means for dealing with the variabilities associated with foods and food processing. While these techniques are relatively new, their ability to enhance HACCP effectiveness are already being demonstrated. For manufacturers that are producing products for which there is no definitive lethal treatment, or for those that have formulations that are based on multiple barriers, integrating quantitative risk assessment techniques into HACCP plan development may be critical to demonstrating product safety. It is unlikely that all food manufacturers will be able to make the transition from qualitative hazard analyzes to QMRA immediately. A significant portion of the food industry are small facilities with limited technical resources, and will have to continue to rely on "default performance and process criteria" (4) developed by government agencies or advisory groups such Codex

Alimentarius. However, the development of user-friendly software that takes the manufacturer through the process of developing HACCP plans, evaluating microbiological risks, and establishing performance standards are already being envisioned as a means for helping the small producer take advantage of these conceptual and technological breakthroughs (8).

Finally, the ability to link HACCP plan results with public health impact is going to be increasingly important in today's world of international trade. Without this capability, it will continue to be extremely difficult to conduct scientifically based assessments of the equivalence of risk management systems. HACCP planning, as a risk management system, functions best when there are sufficient data to make informed decisions. Until HACCP systems can move from a qualitative consideration of hazards to a quantitative assessment of risks, it will not be able to reach its full potential as the most important risk-management system for controlling foodborne disease. Likewise, discussions of the levels of risk control that should be designed into our HACCP plans will continue to be a matter of conjecture. Continuing advances in QMRA can help us reach that goal.

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